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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/344,676	06/25/1999	WILLIAM P. VAN ANTWERP	PD-0310	9328

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EXAMINER
LUKTON, DAVID

ART UNIT	PAPER NUMBER
1653	17

DATE MAILED: 09/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/344,676	VAN ANTWERP ET AL.	
	Examin r	Art Unit	
	David Lukton	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-71* is/are pending in the application.

4a) Of the above claim(s) *8,15-19,26-58,64,69 and 70* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-14,20-23,25,59-63,65-68 and 71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5,14,5,14
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Applicants' election of Group 1 (claims 1-7, 9-14, 20-23, 25, 59-63, 65-68, 71, limited to G1 and G5) is acknowledged, as are the species elections (unmodified human insulin and unmodified human GLP-1). The previous species elections also remain in force (pioglitazone and Genapol).

Applicants' have traversed the restriction requirement by arguing that restriction between dependent inventions is not permissible. Whatever the merits of this argument, the inventions are not dependent, rather, they are independent. The restriction is maintained.

Claims 1-7, 9-14, 20-23, 25, 59-63, 65-68, 71 are examined in part; claims 8, 15-19, 26-58, 64, 69, 70 are withdrawn from consideration.

*

Claims 1-7, 9-14, 20-23, 25, 59-63, 65-68, 71 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 1 is indefinite as to the intended analogs.
- Claim 1 is rendered indefinite by the recitation of "insulin related peptide". In what way must the peptide in question be "related" to insulin?
- In claim 7, the term "GLP-1" and "IGF-1" may be used if accompanied by the full name that these abbreviations represent.
- Claim 20 recites "two or more compounds of agents i, ii or iii". It is not clear what is meant. Does this mean that there is a total of at least two compounds, or

does it mean that when (i) is present, there must be at least two compounds of (i), and when (ii) is present, there must be at least two compounds of (ii), and when (iii) is present, there must be at least two compounds of (iii)...? The same issue applies in the case of claim 71.

- Claim 23 recites "further comprising". This is a limitation which is not required by claim 21, upon which claim 23 depends. Accordingly, either claim 21 should be amended to recite that the carrier is optionally present, or else claim 23 should be written in independent form. The same applies in the case of claim 24 versus claim 21.

*

The following is a quotation of the appropriate paragraphs of 35 U.S.C §102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2) and (4) of section 371(c) of this title before the invention thereof by the applicant for the patent.

Claims 1, 59 and 71 are rejected under 35 U.S.C. §102(e) as being anticipated by Riveley (USP 6153632)

Riveley discloses (e.g., col 4, line 50+) a composition comprising insulin and an insulin sensitizer.

Thus, the claims are anticipated.

*

Claims 1, 59 and 71 are rejected under 35 U.S.C. §102(e) as being anticipated by Knudsen (USP 6,268,343).

Knudsen discloses (e.g., col 168, line 1-17; also claim 36) a composition comprising insulin and GLP-1.

Thus, the claims are anticipated.

*

Claims 1, 59 and 71 are rejected under 35 U.S.C. §102(a) as being anticipated by Smith (WO 98/57636)

Smith discloses a composition comprising insulin and a thiazolidinedione sensitizer

Thus, the claims are anticipated.

*

Claims 1, 59 and 71 are rejected under 35 U.S.C. §102(b) as being anticipated by Tomas (WO 96/02270).

Tomas discloses a composition comprising insulin and IGF-1. Thus, the claims are anticipated.

*

Claims 1, 59 and 71 are rejected under 35 U.S.C. §102(b) as being anticipated by Rink (WO 92/20366).

Rink discloses a composition comprising insulin and amylin.

Thus, the claims are anticipated.

*

Claims 1, 59 and 71 are rejected under 35 U.S.C. §102(e) as being anticipated by Clark (USP 5,783,556).

Clark discloses a composition comprising insulin and IGF-1.

Thus, the claims are anticipated.

*

Claims 1, 59 and 71 are rejected under 35 U.S.C. §102(b) as being anticipated by Cooper (USP 5,641,744).

Cooper discloses (e.g., col 3, line 37+) a composition comprising insulin and amylin.

Thus, the claim is anticipated.

*

Claims 1, 59 and 71 are rejected under 35 U.S.C. §102(b) as being anticipated by Froesch (USP 4,988,675)

Froesch discloses a composition comprising insulin and IGF-1. Thus, the claim is anticipated.

*

Claims 1, 59 and 71 are rejected under 35 U.S.C. §102(b) as being anticipated by Chance (USP 4652548)

Chance discloses a composition comprising insulin and C-peptide. Thus, the claim is anticipated.

*

Claims 1, 59 and 71 are rejected under 35 U.S.C. §102(b) as being anticipated by L'Italien (USP 6,136,784)

L'Italien discloses (e.g., claim 1) a composition comprising insulin and amylin. Thus, the claim is anticipated.

*

The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35

U.S.C. 103.

Claims 1, 59 and 71 are rejected under 35 U.S.C. §103 as being unpatentable over Habener (USP 5,958,909).

Habener discloses that GLP-1 is useful for treating diabetes. Habener does not disclose combining GLP-1 with insulin. However, it would have been obvious to one of ordinary skill to combine GLP-1 with insulin in order to obtain additive effects. Thus, the claim is rendered obvious.

Reference "AJ" (Search Report) was stricken from the IDS. The IDS should be limited to published documents. It is suggested that applicants submit an IDS with the published PCT application listed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 703-308-3213. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1600